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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,695	06/08/2001	John R. Desjarlais	16380-002001	8902
26161	7590	05/31/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/877,695		DESJARLAIS, JOHN R.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Marjorie A. Moran		1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 14-18, 38-50, 60, 61, 67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-18, 38-50, 60-61, and 67-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>2/16/04</u>                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Claims 1-7, 14-18, 38-50, 60-61, and 67-68 are pending. All rejections and objections not reiterated below are hereby withdrawn in view of the amendments and arguments filed 3/13/06.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 14-18, 38-50, 60-61, and 67-68 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The method of the instant claims is computer-implemented and comprises only steps of mathematical manipulation. Claim 1 recites only generating a probability matrix, which is not a physical step. The steps of "generating" and "producing" recited in dependent claims are virtual steps, as made clear in previous office actions and responses, thus the claimed method does not result in a physical transformation of matter. In the absence of a physical transformation of matter, a computer-implemented method MAY be statutory where it recites a practical application; i.e. a concrete, tangible and useful result. Claims 1, 4-7, 14-18, 41-47, 49, and 67 recite only steps of mathematical manipulation but do not recite any actual, concrete result nor any output of a result in a tangible form useful to the user. Claims 2-5, 38-40, 60-61, and 68 recite generating or producing a protein sequence or (combinatorial) library of proteins. Both a sequence and a library are "concrete" results; however, as these results are not output, displayed or otherwise communicated in tangible form to one performing the method, claims 2-5, 40, 60-61, and 68 fail to recite a "tangible and useful" result.

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Claims 48 and 50 recite steps of screening or selecting a protein for a desired activity. As the result of such a screening or selection step (i.e. a protein of desired activity) is not recited nor communicated to a user in a tangible form, claims 48 and 50 also do not recite a concrete, tangible and useful result. As the claims do not result in a physical transformation and fail to recite a concrete, tangible and useful result, they are nonstatutory.. For a discussion of patent eligible subject matter with regard to computer-related inventions, see the Guidelines as set forth at 1300 OG 142 (22 Nov. 2005).

Claims 1, 4, -7, 14-18, 41-47, 49, and 67 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The claims previously recited generating a probability matrix that represents a viable sequence space; i.e. that can be used to predict a "probable" sequence for an energetically favorable conformation of a protein. Determining or predicting an energetically favorable protein sequence or conformation has a well established utility. Claim 1 has been amended to recite generating a probability matrix "to generate a total probability" of each amino acid in a plurality of variant protein sequences, thus it is unclear (a) what the intended result of the method actually IS (the probability matrix, or a total probability, and (b) what the probability matrix is actually intended to represent (probability of what?). While the instant specification discloses several "utilities" for a

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method of protein design, on page 3, there is no disclosure of a utility for a method of merely generating a probability matrix of total fitness "probabilities." As a method of merely generating a data matrix does not have a well established utility and the specification does not disclose a concrete, tangible and useful result for the method of amended claim 1, the claims lack utility.

Claims 1, 4, -7, 14-18, 41-47, 49, and 67 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 14-16, 18, 38-50, 60-61, 65, and 67-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

### ***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon-Fri, 6 am-2:30 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
5/25/06